

USSN 10/511,115 filed 23 June 2005
Atty. Docket No. 1103326-0781
Page 8 of 14

REMARKS

I. Petition for Extension of Time

Applicants herewith petition the Commissioner for Patents to extend the time for response to the Office Action mailed 31 October 2007 for three (3) months from 31 January 2008 to 30 April 2008. Authorization is given to charge the extension of time fee of \$1020.00 (37 C.F.R. §1.136 and §1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

II. Claim Amendments

Claims 3-8 have been amended to clarify that the claimed invention is directed to an aqueous film coating dispersion for pharmaceutical formulations. Support for the claim amendment is provided by the abstract.

Claims 3-8 have also been amended to clarify that the claimed aqueous film coating dispersion is prepared by polymerizing a mixture of monomers and thereby forming a substantially uncrosslinked copolymer. EP 0 288 879 ("EP '879") is discussed in the "Background of the Invention" section of the specification at page 5, lines 21-24:

EP 0228 879 discloses *crosslinked* polymers comprising ethyl acrylate, methyl methacrylate and a hydroxyalkyl ester of methacrylic acid or acrylic acid. Such *crosslinked* esters are not suitable for use in coating pharmaceutical compounds due to the possible presence of residual *crosslinking* agents which are reactive species. (Emphasis added)

Applicants submit that the term "uncrosslinked", as it appears in amended claims 3-8, is not new matter and that the amendment satisfies the written description requirement. When read in its entirety, the specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Specifically, at page 5, lines 27-28 of the specification, it is expressly stated that a purpose of the claimed invention is to provide a new film coating system that does not have the problems of the prior art as discussed in the Background section. One such problem to be resolved by the claimed invention is the problem associated with the use of crosslinked polymers in pharmaceutical coatings as disclosed by EP '879. Accordingly, as illustrated by the working

USSN 10/511,115 filed 23 June 2005
Atty. Docket No. 1103326-0781
Page 9 of 14

examples, the aqueous polymer dispersion of the claimed invention is prepared by polymerizing a mixture of monomers to obtain a substantially uncrosslinked copolymer.

III. Claim Rejections – 35 U.S.C. §112

a. 35 U.S.C. §112, first paragraph

Claim 7-8 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner alleges that the claims are not enabled because the transition phrase “consists of” excludes any other component and/or impurities.

Applicants respectfully disagree. Firstly, claims 7-8 have been amended to clarify that the mixture of monomers is polymerized in the presence of water. Secondly, the transition phrase “consists of”, as it appears in claims 7-8, applies only to the mixture of monomers. In this regard, the Examiner’s attention is directed to M.P.E.P. §2111.03 where is disclosed that:

When the phrase “consists of” appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986).

Therefore, relying on M.P.E.P. §2111.03 and the cited case law, Applicants submit that claims 7-8 comply with the enablement requirement. The location and recitation of the transition phrase “consists of” in claims 7-8 limits only the monomer mixture but it does not exclude other elements from the claim as a whole. Furthermore, as provided by M.P.E.P. §2111.03, the recitation of the transition phrase “consists of” does not close these claims to impurities ordinarily associated therewith.

In view of the specification and working examples, a person of ordinary skill in the art would be able to practice the claimed invention without undue experimentation. Withdrawal of the lack of enablement rejection under 35 U.S.C. §112, first paragraph, is requested.

USSN 10/511,115 filed 23 June 2005
Atty. Docket No. 1103326-0781
Page 10 of 14

b. 35 U.S.C. §112, second paragraph

Amended claims 7-8 render moot the indefiniteness rejection under §112, second paragraph. Claims 7-8 have been amended to clarify that the mixture of monomers is polymerized in the presence of water. Withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is requested.

IV. Claim Rejections – 35 U.S.C. §103

a. claims 3-6 and 31

Claims 3-6 and 31 are rejected under 35 U.S.C. §103(a) as being unpatentable over US 4,056,497 to Reinecke et al. ("Reinecke") in view of US 3,944,513 to Greenwald et al ("Greenwald").

Reinecke discloses a process for the preparation of a *starting material* - an aqueous copolymer dispersions capable of being cross-linked in the presence of alkalis by polymerization of a mixture of monomers. The specific monomers are disclosed at column 1, line 57, to column 2, line 32, of Reinecke.

The only disclosed use of Reinecke's starting material is in the preparation of crosslinked copolymers for use as *intermediates* in the manufacture of *final products* such as lacquers and varnishes, adhesives, pigments, binders, non-woven fabric binders and in sealing and coating material (col. 4, lines 4-11). Applicants submit that the disclosure of the intermediate crosslinked copolymer and final products is irrelevant to the prior art effect of the starting material disclosed at columns 1-3, i.e., the aqueous dispersion comprising an uncrosslinked copolymer. Specifically, there is no disclosure or suggestion by Reinecke of the claimed aqueous film coating dispersion for pharmaceutical formulations, wherein the aqueous film coating dispersion is prepared from the polymerization of a monomer mixture to form a substantially uncrosslinked copolymer.

At page 5 of the Office Action, the Examiner acknowledges that Reinecke is silent about the removal of emulsifier to obtain an aqueous polymer dispersion that is substantially free of residual emulsifying agent. For this purpose, the Examiner relies on Greenwald which is directed to methods for purifying aqueous dispersions of particulate vinyl polymers prepared by emulsion polymerization. However, Greenwald is far removed from pharmaceutical applications

USSN 10/511,115 filed 23 June 2005
Atty. Docket No. 1103326-0781
Page 11 of 14

and, as such, fails to overcome the deficiencies of Reinecke to suggest the claimed aqueous film coating dispersion for pharmaceutical formulations.

For all of the foregoing reasons, Applications submit that the combination of Reinecke and Greenwald fails to disclose or suggest the polymerization of a monomer mixture to form an uncrosslinked copolymer in the preparation of the claimed aqueous film coating dispersion for pharmaceutical formulations. As previously mentioned, Reinecke's disclosed aqueous polymer dispersion is the starting material in the formation of crosslinked copolymers intermediates for use in the manufacture of final products such as lacquers and varnishes, adhesives, pigments, binders, non-woven fabric binders and in sealing and coating material. There is no suggestion of the claimed aqueous film coating dispersion by any of Reinecke's starting material, crosslinked intermediate and final products. Greenwald is unable to overcome the deficiencies of Reinecke to suggest the claimed invention.

A *prima facie* case of obviousness has not been established. Withdrawal of the §103 rejection of claims 3-6 and 31 is requested.

b. claims 9-14

Claims 9-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reinecke in view of Greenwald and US 5,055,306 to Barry et al. ("Barry").

Barry is directed to a sustained-release formulation in the form of effervescent or water-dispersible tablets (col. 1, lines 5-7). In the paragraph bridging columns 4 and 5, it is stated that "sustained-release formulations of pharmacologically active substances have not previously been presented, or at least successfully presented, in the form of effervescent or water-dispersible tablets". To solve this problem, Barry discloses a specific coating covering substantially the whole surface of a core containing granules of a pharmaceutically active and effervescent or water-dispersible ingredients. As disclosed at column 3, lines 48-53, the coating comprises the following: 100 parts of a water insoluble but water swellable acrylic polymer, and from 20 to 70 parts of a water soluble hydroxylated cellulose derivative.

The Examiner alleges that it would have been obvious at the time the claimed invention was made to replace the coating disclosed by Barry with one comprised of the acrylic ester copolymer disclosed by Reinecke to arrive at the claimed invention.

USSN 10/511,115 filed 23 June 2005
Atty. Docket No. 1103326-0781
Page 12 of 14

Each of the rejected claims 9-14 is dependent, either directly or indirectly, on any one of claims 3-8 which are directed to an aqueous film coating dispersion.

At the bottom of page 6 of the Office Action, the Examiner states that the rationale for combining Barry with Reinecke is the disclosure by Reinecke of an acrylic ester copolymer that may be used as pressure-sensitive adhesives of high stability. The Examiner cites lines 6-7 of the Abstract.

Applicants respectfully submit that the Examiner's reliance on Reinecke is fatally flawed and represents reversible error. Specifically, lines 6-7 of the Abstract pertain to the disclosure at column 4, lines 4-18, of Reinecke which is directed to the cross-linked copolymers which serve as intermediate products in the manufacture of final products such as a pressure-sensitive adhesive for self-adherent floor-coverings, etc. As such, the Examiner's reliance on Reinecke's crosslinked pressure-sensitive adhesives is far removed from the claimed aqueous film coating dispersion which is prepared by polymerizing a mixture of monomers to forming an uncrosslinked copolymer.

For all of the foregoing reasons, it is submitted that the Examiner's rationale for combining Reinecke with Barry is clear evidence that a *prima facie* case of obviousness has not been established. The invention of claims 9-14 is characterized by a film coating that is prepared by applying the aqueous polymer dispersion of claims 3-8 that is prepared by the polymerization of a monomer mixture to obtain an uncrosslinked copolymer. The combination of the Reinecke (Abstract, lines 6-7), Greenwald or Barry, whether taken alone or in combination, does not suggest the claimed invention. Nor would the cited combination result in the claimed invention. Withdrawal of the §103 rejection of claims 9-14 is requested.

c. claims 15 and 16

Claims 15 and 16 are rejected under 35 U.S.C. §103(a) as being unpatentable over the combined teaching of Reinecke, Greenwald, Barry, US 5,939,578 to Chen ("Chen") and US 4,957,745 to Jonsson et al. ("Jonsson").

Claims 15 and 16 are directed to the active ingredients of the claimed pharmaceutical formulation. The Examiner notes that Barry does not teach the beta-blocking adrenergic agent to

USSN 10/511,115 filed 23 June 2005
Atty. Docket No. 1103326-0781
Page 13 of 14

be metoprolol salts such as tartrate, succinate, fumarate or benzoate salt. For this purpose, the Examiner relies on Chen and Jonsson.

Claims 15 and 16 are dependent on claim 14 which is itself indirectly dependent on any one of claims 3-8. The patentability of claim 14 is discussed in the preceding Section IV(b), above.

Applicants submit that neither Chen nor Jonsson overcomes the failure of the combination of Reinecke, Greenwald and Barry to render the pharmaceutical formulation of claims 15-16 obvious for the reasons given in the preceding Section IV(b), above. Withdrawal of the §103 rejection of claims 15 and 16 is requested.

d. claims 27-30 and 32

Claims 27-30 and 32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reinecke in combination with Greenwald, US 6,646,046 to Contrada et al. ("Contrada") and GB 1 141 165 ("Zellstoffwerke").

With respect to the limitations of dependent claims 27-30 and 32, the Examiner acknowledges that Reinecke does not teach the repeating units in component (e), i.e., Formula II, and an alkoxy group with C1-20 for the terminal group. For this purpose, the Examiner relies on Contrada and Zellstoffwerke.

Contrada is directed to an aqueous pressure-sensitive adhesive composition. The Examiner relies specifically on the disclosure of the monomer M₁ disclosed at column 3, lines 38-54. Zellstoffwerke is directed to the manufacture of acrylic films. The Examiner relies on the disclosure by Zellstoffwerke of an ester of a polyethoxylated product containing at least one acrylic or methacrylic ester group. The Examiner alleges that the cited compounds of Contrada and Zellstoffwerke, respectively, encompass component (e) of Reinecke.

Each of claims 27-30 and 32 is directly dependent on claim 4, 6 or 8. It has been established in the preceding Section IV(a), above, that Reinecke does not render obvious the claimed aqueous film coating dispersion. Applicants submit that neither Contrada nor Zellstoffwerke overcomes the failure of Reinecke to render the pharmaceutical formulation of claims 4, 6 or 8 obvious for the reasons given in the preceding Section IV(a), above. Withdrawal of the §103 rejection of claims 27-30 and 32 is requested.

USSN 10/511,115 filed 23 June 2005
Atty. Docket No. 1103326-0781
Page 14 of 14


CONCLUSION

In view of the claim amendments and remarks herein, the application is in condition for allowance.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

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Respectfully submitted,


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